K955543

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510(k) Summary

FUKUDA DENSHI FF sonic model UF-3500

General Purpose Ultrasound Scanner

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Device Name:

Proprietary Name:

FF sonic model UF-3500 General Purpose Ultrasound Scanner

Common Name:

General Purpose Ultrasound Scanner

Classification Name:

System, Imaging, Pulsed Echo, Ultrasonic

Legally Marketed Device:

FUKUDA DENSHI FF sonic model UF-4500 General Purpose Ultrasound Scanner (K922208)

Description:

The model UF-3500 is a portable, General Purpose Ultrasound Scanner. This ultrasonic device is designed to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interface and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. The resulting information is displayed on the system's 7 inch diagonal video monitor as a 16 level greyscale B-Mode image.

The system provides user flexibility for different measurement and calculations that are incorporated into the unit. General measurements include distance, area, circumferential length, volume, and angle. Fetal calculations include gestational week, expected date of confinement, and fetal weight. All fetal measurements are derived from either Tokyo University's system, Osaka University's system or the American/European system; the same systems used on the UF-4500

The UF-3500 can be used with any of eight (8) different linear transducers, only one of which may be active at any one time. An option is provided that will allow two probes to be simultaneously connected to the UF-3500; again, only one of which may be active at any time.

Intended Use:

This device is intended to be used for applications in fetal, abdominal, intra-operative, pediatric, small organ, trans-rectal, and peripheral vessel scanning. Ultrasonic probes are available to obtain images either transrectally or intraoperatively. It is intended to by used by or on the order of a physician or similarly qualified health care professional. The UF-3500 is intended to be used in a doctors office and all hospital environments; ER ICU, CCU, OR, etc. This device is intended to be use on any patient; neonate, pediatric, or adult; where the placement and positioning of the transducer does not interfere with or complicate the treatment of the patient. This device is not intended for home use.

The UF-3500 applies ultrasound energy though the abdominal wall to obtain an image of the fetus and abdominal organs that can be used to determine the gestational age of the fetus or to detect abnormalities of the fetus or abdominal organs.

The UF-3500, when used with the transrectal probe, applies ultrasound energy though the rectal wall to obtain an image of the abdominal organs that can be used to detect abnormalities of these organs.

Technological Characteristics

The UF-3500 incorporates a microprocessor in the same manner as the predicate device. Transducers are limited to linear probes, again the same probes available for the predicate device. (Transrectal and intraoperative probes are added to the UF-4500 under a separate 510(k)filing.)

These technological differences do not effect the safety or efficacy of the device. Any safety issues that may be raised by a software controlled medical device are the same issues already addressed by the predicate device and are addressed in the systems hazard analysis and in the system validation.

Testing:

Laboratory testing was conducted to validate and verify the FUKUDA DENSHI FF sonic model UF-3500 General Purpose Ultrasound Scanner met all design specifications and was substantially equivalent to the FUKUDA DENSHI model UF-4500. This testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewer Guidance Document for Premarket notification Submissions" Draft Guidance Document. Additional testing was performed to demonstrate compliance with the voluntary AIUM "Acoustic Output Measurement and Labeling Standard for Diagnostic Ultrasound Equipment", 1992 and ANSI/AAMI ES1-1993, "Safe current limits for electromedical apparatus". Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation.

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of

the device may be critical to the proper management of the patient.

The other area of concern is the safety of the patient in that the device intentionally inputs energy, projects a pulsed sound beam, into body tissue. The UF-3500's acoustic out power levels were tested and found to be below the pre-amendment acoustic power intensity levels listed in the "Revised 510(k) Diagnostic Ultrasound Guidance for 1993" document.

So, the areas of risk for this device are the same as other devices in this class, and are the following:

- Electrical shock
  Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart, and possibly leading to the onset of cardiac arrhythmias.
- Excessive Ultrasound Energy
  Excessive ultrasound energy can cause localized heating and possible tissue damage.
- Misdiagnosis
  - Inadequate design of the signal processing and measurement circuitry or program can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
  - Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

The design of the UF-3500 has taken into account all the above. The device is designed to meet UL 601, CSA 22.2 and AAMI standards for electrical safety for medical equipment to prevent the possibility of excessive electrical leakage current to the patient.

Conclusion:

The conclusions drawn from the laboratory testing of the FUKUDA DENSHI FF sonic model UF-3500 General Purpose Ultrasound Scanner demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, the FUKUDA DENSHI model UF-4500.